

Application No.: 10/658,962  
Attorney Docket No.: 49321-102  
First Applicant's Name: Mendy S. Maccabee  
Application Filing Date: September 8, 2003  
Office Action Dated: October 28, 2008  
Date of Response: February 24, 2009  
Examiner: Jennifer M. Kim

### **REMARKS**

Claims 1-23 were originally filed in this application. Claims 9, 10, and 22 were previously withdrawn from consideration as being drawn to a nonelected invention and claims 13-20 and 23 were previously cancelled. In this response, claims 1, 7, 8, and 21 have been amended, claims 2-5, 11, and 12 cancelled, and new claims 24-28 added. Support for the amendments and added claims is found throughout the specification as originally filed. No new matter has been added. Accordingly, claims 1, 6-8, 21, and 24-28 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

### ***Claim Rejections-35 U.S.C. § 112***

Claims 2, 7, and 11 stand rejected under 35 U.S.C. §112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. The Office states that a broad range or limitation in the same claim is considered indefinite since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired (MPEP § 2173.05(c)). Specifically, the Office states that (1) claim 2 recites the broad recitation “ciliated epithelial structure” and also “including respiratory epithelium,” which is the narrower statement of the limitation; (2) claim 7 recites the broad recitation “an indicator” and also “including of the lamina propria... including causing a greater density...including sinus bone morphometry,” which is the narrower statement of the limitation; and (3) claim 11 recites the broad recitation “vitamin A” and also “retinoic acid,” which is the narrower statement of the limitation.

In order to expedite prosecution, claims 2 and 11 have been cancelled without prejudice, thereby rendering any rejection of those claims moot. Claim 7 has been amended to

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delete the phrases "including lamina propria," "including causing a greater density of regenerated cilia," and "including sinus bone morphometry," rendering the stated rejection of that claim moot. Other amendments made to claim 7 improve form and are not made to overcome any rejection.

In view of the above, withdrawal of the indefiniteness rejection of claims 2, 7, and 11 is respectfully requested.

***Claim Rejections-35 USC §103(a)***

Claims 1-8, 11, 12, and 21 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Biesalski (U.S. 5,556,611) in view of Belloni (6,339,107). Specifically, the Office maintains that Biesalski does not expressly teach a depot formulation of retinoic acid or a cause of ciliated epithelial structure damage due to surgical intervention, but that it would be obvious to one of skill to modify the aerosol formulation of Biesalski to a topical depot formulation as taught by Belloni. Applicants disagree with this rejection.

Claims 2-5, 11, and 12 have been cancelled, rendering the rejection of those claims moot. Claim 1 has been amended to recite a method for treating "a sinus disease or promoting sinus wound healing in a subject in need thereof." Support for this amendment is found, among other places, in paragraph 10 of the specification as originally filed. Applicants submit that the cited references fail to support even a *prima facie* case of obviousness because either alone, or in combination, they lack any disclosure of these treatment indications.

Biesalski discloses an aerosol formulation that is used to locally administer retinoic acid to mucous membranes of the respiratory tract to avoid the toxicity associated with systemic administration (column 1, line 54 to column 2, line 20). Biesalski states that the diseases his preparation would be suitable to treat include, "bronchial carcinomas, acute and chronic

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bronchitis, acute and chronic functional disturbances due to impairment of the tracheobronchial epithelium following inhalation of dusts and gases damaging the mucous membranes, and bronchopulmonary dysplasia (column 10, lines 38-44). Nowhere does Biesalski teach, describe, or even suggest using his aerosol for treatment of a sinus disease, or promotion of sinus wound healing. Indeed, Biesalski fails to teach, describe, or even suggest treatment of conditions affecting the upper airway (portion of the airway above the vocal cords), of which sinus diseases and sinus wounds are included. All of the diseases Biesalski describes are diseases of the lower airway (portions of the airway below the vocal cords). In addition, Biesalski fails to teach, describe, or even suggest a patient population in need of treatment from a sinus disease or sinus wound. Because Biesalski wholly fails to address a population of patients in need of treatment for specific conditions, which conditions Biesalski also fails to describe, it cannot be said that Biesalski renders the instant claims obvious.

Belloni also fails to teach the treatment of sinus disease or promotion of sinus wound healing in subjects in need thereof, and thus does not cure the deficiency in Biesalski. Rather, Belloni describes the use of 13-cis-retinoic acid to treat lung disorders such as chronic obstructive pulmonary disorders, including chronic bronchitis, emphysema, and asthma.

In view of the above, withdrawal of the rejections under 35 U.S.C. §103(a) are respectfully requested.

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### **CONCLUSION**

In view of the foregoing amendments and remarks, Applicants respectfully request entry of the present Amendment and allowance of the amended claim set provided herein. The Examiner is encouraged to phone Applicants' attorney, Barry L. Davison, to resolve any outstanding issues and expedite allowance of this application.

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